IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV;
3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF JAMES GODDARD TAKEN MARCH 28 & 29, 2013

BSC Designations	Objection	Plaintiffs Counter Designation
jg032913, (Pages 488:13 to 495:2) *** Q. I want to talk generally about the process of research and development of a new product like the slings or the treatments, the devices for pelvic organ prolapse. In general what are the steps to bring a product through the research and development process? A. There's a very thorough process, and at a high level we collect input to help design or define what that design should be, then verify that design and ultimately validate, and in collecting that input per se, we're working closely with physicians, and specifically with Solyx and the Pinnacle and Uphold, these were products that were brought in to BSC as far as an idea, a design that these physicians had in mind. So Dr. Mamo brought to us that Solyx idea. The Uphold product was something that Dr. Goldberg had developed on his own, in looking at a way to create a mesh shape that would work best for a		*[Counter Designation to 489:5-490:22]* *jg032813, (Pages 178:17 to 179:1)* *178* *how do you measure the erosion rate in a cadaver? You don't, do you?* *A. We don't, no.* *Q. Okay. I didn't think you could do that. You can't validate that failure effect mode, right, and the rate of it?* *A. No, we wouldn't be assessing it at* *179* *that point, no.*

24 hysteropexy procedure, and Dr. Miller brought 490 1 forth an idea around the placement of the arms of 2 the mesh profile in the sacrospinous ligament. 3 So in those products or programs, 4 we worked closely with those physicians to 5 further develop that idea, and we also brought in 6 multiple other physicians to also take a look at 7 how we were approaching this, just to confirm 8 that we were hearing from these one or -- you 9 know, one physician that brought the idea that 10 that makes sense, and the way we proceed with 11 that is through bioskills labs, which are working 12 with cadavers basically, and our frequency in 13 doing that would happen almost once a month or so 14 to iterate that process. So a lot of that 15 information goes into the input documents, if you 16 will. We create a market specification, a 17 product specification. We start our risk 18 management aspects of it. So we look at if we're 19 moving toward this design what potential failures 20 could occur. So we start assessing that early on 21 to make sure that we put the controls in place to 22 minimize the risk associated with that. ***		
502:17-507:1 *** 503 15 What advantages did Uphold have 16 compared to the trocar-based systems that were on 17 the market prior to that? 18 A. The Uphold product also utilized 19 the Capio device. So the single incision 20 approach was able to be achieved, no blind trocar 21 passage, plus the Uphold basically had mesh only 22 where it was needed, so it was a smaller mesh 23 footprint or amount of mesh that's implanted. ***		*[Counter Designation to 503:15-23]* *jg032813, (Pages 63:20 to 64:3)* *63* *20 What other types of ideas have you submitted* *21 other than the adjustability of the sling idea?* *22 A. A trocar idea that had an* *23 extendable member to it. So most trocars are* *24 fairly fixed in their size and shape. In this* *64* *1 case, there was an actuator that allowed the tip* *2 or the end of that trocar to be extended after it* *3 was positioned in the body.* *jg032813, (Page 68:9 to 68:14)* *68* *9 Q. And you were trying*

		to design a *10 better trocar to avoid certain complications that* *11 you knew were associated with the trocar, am I* *12 right?* *13 A. We did not have a situation where* *14 there were issues with the current product.*
jg032913, (Page 507:4 to 507:9) 507 4 What did Boston Scientific 5 ultimately conclude about the biocompatibility of 6 the mesh used in the Uphold and Pinnacle devices? 7 A. These materials were found to be 8 biocompatibility based upon the test acceptance 9 criteria.		*30(b)(6) Deposition of James Goddard taken February 18, 2015 at 321:15-322:3 [Counter-Designation to 507:4-9]]* *15 You testified clearly to this jury* *16 that the company complied with ISO-10993, didn't* *17 you?* *18 A. Yes.* *19 Q. And you testified that the company* *20 routinely complied with ISO-10993, correct?* *21 A. Yes.* *22 Q. And ISO-10993 is a standard battery of* *23 biocompatibility testing that is done, or* *24 supposed to be done for every implantable* *25 medical device in the world at this point,* *322* *1 that's regulated anyhow? It's the test, or the* *2 battery of them, right?* *3 A. Yes.* *328:9-11 [Counter-Designation]* *9 Q. Let me show you a document that I'm* *10 going to mark as Exhibit Number 47 to your* *11 deposition.* 330:1-331:2 [Counter-Designation]

		1 Q. All right. Who is Linda Woodhull -- *2 Lindsay Woodhull?* *3 A. She works in the biocompatibility* *4 group.* *5 Q. Somebody that knows about* *6 biocompatibility?* *7 A. Yes.* *8 Q. Who is Michelle Berry?* *9 A. Michelle Berry works in the regulatory* *10 affairs group.* *11 Q. That's right. She's a regulatory* *12 compliance.* *13 Who is Joe -- I don't even know how to* *14 pronounce that Raneri?* *15 A. Are you asking?* *16 Q. I'm asking who he is.* *17 A. Joe Raneri was involved with a program* *18 at Boston Scientific as a core team lead.* *19 Q. "Hi Michelle, Sorry to take all day to* *20 get back to you, my day has been full of* *21 meetings as well. Here is a summary of the* *22 issue. As you know we have many mesh products,* *23 Lynx, Pinnacle, Solyx, et cetera. They all use* *24 the same Marlex HGX-030-01."* *25 That's the Marlex mesh that you talked* *331* *1 about the MSDS sheet with, right?* *2 A. Yes.* 334:15-20 [Counter-Designation] *15 Q. Okay. Let's go on for a minute.*

		16 "ISO-10993-12 establishes the sample preparation *17 requirements. We are not in compliance with* *18 ISO-10993-12 (2009), the most recent version,* *19 because the data does not include both polar and* *20 non-polar extract."* *334:23-335:17 [Counter-Designation]* *23 Q. "We are not in compliance with the* *24 2007 revision either." That's on top?* *25 A. Yes.* *335* *1 Q. That's two years before it was put on* *2 the market, right?* *3 A. Yes.* *4 Q. "ISO-10993-10 is for the sensitization* *5 studies themselves. We are not compliant with* *6 ISO-10993-10, 2009 or 2007, because of the lack* *7 of a positive control in the NAMSA Report.... I* *8 need to find a copy of the 2002 version because* *9 it is not available on IHS." What is IHS?* *10 A. It's basically a portal in order to* *11 access the standards.* *12 Q. It's part of the computer system at* *13 Boston Scientific, program?* *14 A. Yes.* *15 Q. That has documents on it?* *16 A. It's something that Boston Scientific* *17 uses to access the standards documents, yes.* *337:9-339:25 [Counter-Designation]*

		9 Q. Well, it says up at the top of this, *10 "Back in 2003 when R&D still handled* *11 biocompatibility testing." R&D was your* *12 department, wasn't it? We'll highlight it, show* *13 it to him, right here. It says "Back in 2003."* *14 When you first started with Boston Scientific,* *15 was biocompatibility testing done at -- in R&D?* *16 A. We did not do the testing, no.* *17 Q. I was asking when you started was it* *18 being done in R&D?* *19 A. I don't recall specifically here, but* *20 in 2003 when this was being done, I was, again,* *21 not there. It may have been something that R&D* *22 requested the testing to be done rather than* *23 rely on the biocompatibility group to initiate* *24 it.* *25 Q. Well, what I'm getting at is there* *338* *1 wasn't a biocompatibility group in 2003, was* *2 there?* *3 A. I don't recall specifically.* *4 Q. Do you recall if the biocompatibility* *5 group was in place when you came on?* *6 A. Yes.* *7 Q. Were they?* *8 A. I believe so.* *9 Q. And that would have been 2000?* *10 A. It was late 2003 and beyond.* *11 Q. Turn over to Page*

		581 on the Bates *12 stamp. See the top e-mail?* *13 A. Yes.* *14 Q. From Joseph Conkey? Yes?* *15 A. I see his name here, yes.* *16 Q. Who is he?* *17 A. He is a quality manager.* *18 Q. And it's sent to a group of folks,* *19 including yourself, right?* *20 A. Yes.* *21 Q. "Mesh sterilization CAR from* *22 corporate."* *23 What's a CAR?* *24 A. The CAR basically is looking for an* *25 action or a follow-up.* *339* *1 Q. What does CAR stand for, sir?* *2 A. Corrective action request.* *3 Q. Correct. Corrective action request.* *4 When were those put into place at Boston* *5 Scientific?* *6 A. I don't know the specific start date* *7 for that.* *8 Q. Well, CARs come about because of* *9 review at the corporate level when they find a* *10 deficiency and send it down with a corrective* *11 action request, right?* *12 A. The corrective action requests occur* *13 within a division within a group. It's not* *14 specific to a corporate activity.* *15 Q. If you look at the bottom e-mail, "A* *16 site-to-site CAR has been received from*

		17 corporate." *18 What does "corporate" mean to you?* *19 A. The corporate means a corporate group* *20 that represents the company-wide.* *21 Q. "This CAR has been assigned* *22 Marlborough" number -- and Marlborough 2010 09* *23 03, with an institution date -- initiation date,* *24 excuse me, of 2nd September of 2010, and a due* *25 date of 17 September 2010.* *340:1-342:1 [Counter-Designation]* *1 Did I read that correctly?* *2 A. Correct.* *3 Q. Do you believe that just being* *4 inadvertent and not following the ISO standards* *5 is some type of justification for not doing the* *6 test right?* *7 MR. KLEFFNER: Object to the form.* *8 A. For not doing the test? It was* *9 believed at the time that tests were being done* *10 correctly.* *11 BY MR. PIRTLE:* *12 Q. Who believed that?* *13 A. Based upon the documentation that has* *14 followed, there was belief that the appropriate* *15 test was in place.* *16 Q. Well, the belief was wrong, wasn't it?* *17 A. People make mistakes, and we took* *18 action from a company perspective when we* *19 uncovered that fact,*

		assessed what was the issue, and took steps to correct it.
jg032913, (Pages 507:11 to 508:8) 507 What is the material that's used for the mesh that's in Pinnacle and Uphold? A. Polypropylene. Q. Do you believe that's an appropriate choice for Boston Scientific's mesh devices? A. Yes. Q. Why, why do you believe that's an appropriate material? A. It is a material that has a long history of use not only in many medical devices but also for implanted products or implanted materials. So it's been in the hernia market. There are polypropylene sutures that have been 508 around a number of years as well. And then the predicate vaginal meshes were of polypropylene for the most part. So we decided that there's a body of evidence to suggest that that would be an appropriate material. We did our own testing to basically confirm that aspect, and that's, you know, what supports its use for safety and efficacy.	507:11-508:8 FRE 401, 402, 403, 701, 702	
jg032913, (Pages 530:13 to 531:12) 530 Q. In general when you're involved with designing and developing products like Pinnacle or Uphold, what is the focus, what are you trying to achieve when you're involved in that process? A. We are listening to the customer, so we're basically getting feedback or input from physicians on device design, and we are looking to incorporate what they see as user interface values in their patient safety aspects into these designs, and that's evident in the Pinnacle and Uphold design where we moved away from this blind 531 trocar passage to the single incision Capio. So we're offering the customer an option to a surgical procedure looking to incorporate their input into that. Q. Do you believe that Boston Scientific's devices, the medical devices that you've been involved with like Pinnacle and	530:13-531:12 FRE 401, 402, 403, 701, 702	

8 Uphold and Solyx, are safe? 9 A. I do. 10 Q. Do you believe that those products 11 are effective options for doctors? 12 A. I do.		

1. **Counter Exhibits**

   a. Exhibit 47 to the Deposition of James Goddard taken February 18, 2015.

DATED: June 26, 2015

Respectfully Submitted,

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 20176500
Shawn P. Fox
State Bar No. 24040926
Clint Casperson
State Bar No. 24075561
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 2176500
Shawn P. Fox
Clint Casperson
State Bar No. 24075561
State Bar No. 24040926
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com